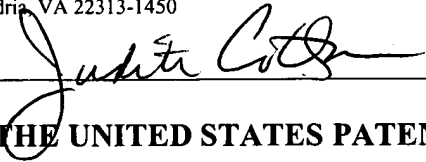


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PATENT
Attorney Docket No.: 10692V-000220US

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By: 

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Michael A. Adams et al.

Application No.:

Filed: February 23, 2004

For: COMBINATION THERAPY FOR
TREATMENT OF ERECTILE
DYSFUNCTION

Examiner:

Art Unit:

INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §1.97 and
§1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Application No. 09/177,711, filed 10/23/1998 (Attorney Docket No. 10692V-000210US). It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

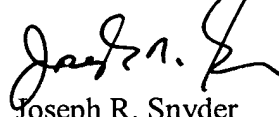
As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement.

However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,


Joseph R. Snyder
Reg. No. 39,381

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

Complete If Known

Application Number	
Filing Date	
First Named Inventor	Michael A. Adams et al.
Art Unit	1617
Examiner Name	Wang, S.
Attorney Docket Number	

U.S. PATENT DOCUMENTS

Examiner	Cite No. ¹	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
						<input type="checkbox"/>

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AA	Campbell et al., "Prevention of Tolerance to Nitroglycerin Patches by Overnight Removal," <i>Am J Cardiol</i> , 60:271-275 (1987)	
	AB	Parker, "Nitrate Tolerance," <i>Am J Cardiol</i> , 56:281-311 (1985)	
	AC	Packer et al., "Hemodynamic Factors Limiting the Response to Transdermal Nitroglycerin in Severe Chronic Congestive Heart Failure," <i>Am J Cardiol</i> , 57:260-267 (1986)	
	AD	Flaherty, "Hemodynamic Attenuation and the Nitrate-Free Interval: Alternative Dosing Strategies for Transdermal Nitroglycerin," <i>Am J Cardio</i> , 56:321-371 (1985)	
	AE	Armstrong et al., "Blood Levels After Sublingual Nitroglycerin," <i>Circulation</i> , 59(3):585 (1979)	
	AF	Nabel et al., "Effects of Dosing Intervals on the Development of Tolerance to High Dose Transdermal Nitroglycerin," <i>Am J Cardiol</i> , 63:663-669 (1989)	
	AG	Lin et al., "Crossover from Intravenous to Transdermal Nitroglycerin Therapy in Unstable Angina Pectoris," <i>Am J Cardiol</i> , 56:742-748 (1985)	

Examiner
SignatureDate
Considered

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PTO/SB/08A (08-00)

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Substitute for form 1449A/PTO <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(use as many sheets as necessary)</p>		Complete If Known	
		Application Number	
		Filing Date	
		First Named Inventor	Adams et al.
		Group Art Unit	1617
		Examiner Name	Wang, S.
		Attorney Docket Number	
Sheet	1	of	1

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	AA	5877216		Place et al.	03/02/99	
	AB	6306841		Place et al.	10/23/01	
	AC					
	AD					
	AE					
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FOREIGN PATENT DOCUMENTS								
Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	AU							
	AV							
	AW							
	AX							
	AY							
	AZ							
	BA							

Examiner Signature		Date Considered	
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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ATTORNEY DOCKET NO.

APPLICATION NO.

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

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APPLICANT

Michael A. Adams, et al.

FILING DATE

GROUP

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING D. IF APPROPRIATE
	AA	5,278,192	01/11/94	Fung et al.	514	645	
	AB	5,439,938	08/08/95	Snyder et al.	514	565	
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATI YES
	AL	WO 94/16729	4-Aug-94	WIPO			
	AM	WO 96/32118	17-Oct-96	WIPO			
	AN						
	AO						
	AP						
	AQ						

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	Linnet, Otto I. et al., "Efficacy and Safety of Intracavernosal Alprostadil in Men with Erectile Dysfunction," <i>New England Journal of Medicine</i> , 334(14):873-877 (1996).
	AS	Padma-Nathan, Harin et al., "Treatment of Men with Erectile Dysfunction with Transurethral Alprostadil," <i>New England Journal of Medicine</i> 336(1):1-7 (1997).
	AT	Ferreira, Sérgio H. et al., "The molecular mechanism of action of peripheral morphine analgesia: stimulation of the cGMP system via nitric oxide release," <i>European Journal of Pharmacology</i> 201:121-122 (1991).

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO.	APPLICATION NO.
INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)		APPLICANT Michael A. Adams, et al.	
		FILING DATE	GROUP
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
AU	Brock, Gerald et al., "Intracavernous Sodium Nitroprusside: Inappropriate Impotence Treatment," <i>Journal of Urology</i> 150:864-867 (1993).		
AV	Duarte, I.D.G. et al., "Peripheral analgesia and activation of the nitric oxide-cyclic GMP pathway," <i>European Journal of Pharmacology</i> , 186:289-293 (1990).		
AW	Ferreira, Sertgio H. et al., "Blockade of hyperalgesia and neurogenic oedema by topical application of nitroglycerin," <i>European Journal of Pharmacology</i> , 217:207-209 (1992).		
AX	Duarte, Igor D.G. et al., "Analgesia by direct antagonism of nociceptor sensitization involves the arginine-nitric oxide-cGMP pathway," <i>European Journal of Pharmacology</i> , 217:225-227 (1992).		
AY	Maurice, D.H. and Haslam, R.J. "Molecular Basis of the Synergistic Inhibition of Platelet Function by Nitrovasodilators and Activators of Adenylate Cyclase: Inhibition of Cyclic AMP Breakdown by Cyclic GMP," <i>Molecular Pharmacology</i> , 37(5):671-681 (1990).		
AZ	Maurice, Donald H. et al., "Synergistic actions of nitrovasodilators and isoprenaline on rat aortic smooth muscle," <i>European Journal of Pharmacology</i> , 192:235-242 (1991).		
AR2	Maurice, Donald H. and Haslam, Richard J., "Nitroprusside enhances isoprenaline-induced increases in cAMP in rat aortic smooth muscle," <i>European Journal of Pharmacology</i> , 191:471-475 (1990).		
AS2	Jang, Elliott K. et al., "Synergistic inhibitory effects of atriopeptin II and isoproterenol on contraction of rat aortic smooth muscle: roles of cGMP and cAMP," <i>European Journal of Pharmacology</i> , 250:477-481 (1993).		
AT2	von Heyden, Burkhard et al., "Intracavernous Pharmacotherapy for Impotence: Selection of Appropriate Agent and Dose," <i>Journal of Urology</i> , 149:1288-1290 (1993).		
AU2	Hempelmann, Ralf, G. et al., "Non-synergistic relaxant effects of vasoactive intestinal polypeptide and SIN-1 in human isolated cavernous artery and corpus cavernosum," <i>European Journal of Pharmacology</i> 276:277-280 (1995).		
AV2	Martinez-Pineiro, Luis et al., "Preliminary Results of a Comparative Study with Intracavernous Sodium Nitroprusside and Prostaglandin E1 in Patients with Erectile Dysfunction," <i>Journal of Urology</i> 153:1487-1490 (1995).		
AW2	Sun,, Jim X. et al., "Comparative Pharmacokinetics and Bioavailability of Nitroglycerin and its Metabolites from Transderm-Nitro, Nitrodisc, and Nitro-Dur II Systems Using a Stable-Isotope Technique," <i>J. Clin. Pharmacol.</i> 35:390-397 (1995).		
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INFORMATION DISCLOSURE CITATION
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APPLICANT

Michael A. Adams, et al.

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AX2

Strejan, G.H. et al., "Suppression of Chronic-Relapsing Experimental Allergic Encephalomyelitis in Strain-13 Guinea Pigs by Administration of Liposome-Associated Myelin Basic Protein," *Journal of Neuroimmunology* 7:27-41 (1984/85).

AY2

Heaton, J.P.W. et al., "Topical Glyceryltrinitrate Causes Measurable Penile Arterial Dilation in Impotent Men," *Journal of Urology* 143:729-731 (1990).

AZ2

Kim, Noel N. et al., "Altered Contractility of Rabbit Penile Corpus Cavernosum Smooth Muscle by Hypoxia," *Journal of Urology* 155:772-778 (1996).

EXAMINER

DATE CONSIDERED